DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

C.R. Bard, Inc.
% Mr. Reily Inman
Regulatory Affairs Associate
605 North 5600 West
SALT LAKE CITY UT 84116

March 30, 2015

Re: K150529
Trade/Device Name: Site-Rite Prevue and Prevue+ Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: February 27, 2015
Received: March 2, 2015

Dear Mr. Inman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150529

Device Name
Site-Rite Prevue Ultrasound System, Site-Rite Prevue+ Ultrasound System

Indications for Use *(Describe)*
The Site-Rite Prevue Ultrasound System is intended to provide ultrasound imaging of the human body. Specific clinical applications include:

- Adult Cephalic
- Neonatal Cephalic
- Pediatric
- Peripheral Vessel

The Site-Rite Prevue+ Ultrasound System is intended to provide ultrasound imaging of the human body. Specific clinical applications include:

- Adult Cephalic
- Neonatal Cephalic
- Pediatric
- Peripheral Vessel

The gel cap is intended for use as an ultrasound coupling medium for use with the Site~Rite Prevue® Ultrasound System. The device is intended for use with pediatrics and adults.

The needle guides are intended to provide guidance for a needle to intersect an ultrasound beam at a fixed distance below the skin to assist the medical practitioner in placing the tip of a needle in a specific structure. This device is intended for use with pediatrics and adults.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Site~Rite Prevue® Ultrasound System and Site~Rite Preve+® Ultrasound System (includes non-detachable, linear, 52 element probe with no unique operating controls)

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CW D	Color Doppler (CD)	Combined (Specify)	Other† (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (abdominal, thoracic, and vascular)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	**P**						
	Small Organ (breast, thyroid, parathyroid, testicles, prostate, uterus, ovary)							
	Neonatal Cephalic	**P**						
	Adult Cephalic	**P**						
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-Esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel	**P**						
	Other (Specify)							

N = new indication; **P =** previously cleared by FDA; **E =** added under this appendix

†Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Prescription Use (Per 21 CFR 801.109)

510(k) Summary

510(k) Summary
21 CFR 807.92

The Site~Rite Prevue® Ultrasound System and the Site~Rite Prevue+® Ultrasound System

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General Provisions	Submitter Name:	Bard Access Systems, Inc.
	Submitter Address:	605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Reily Inman Regulatory Affairs Associate Bard Access Systems, Inc. reily.inman@crbard.com 801.522.5937 801.522.5425
	Date of Preparation:	February 27, 2015

Subject Devices for Which Clearance is Requested:

Subject Device(s)	Trade Names:	**Site~Rite Prevue® Ultrasound System** **Site~Rite Prevue+® Ultrasound System**
Classification Name:	IYO 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System ITX 21 CFR 892.1570 Diagnostic Ultrasonic Transducers Class II, Radiology	
Common Name:	IYO 21 CFR 892.1560 System, Imaging, Pulsed Echo, Ultrasonic ITX 21 CFR 892.1570 Transducer, Ultrasonic, Diagnostic	

Predicate Device	Trade Name:	Site~Rite Prevue® Ultrasound System
Classification Name:	IYO 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System ITX 21 CFR 892.1570 Diagnostic Ultrasonic Transducers Class II, Radiology	
Common Name:	IYO 21 CFR 892.1560 System, Imaging, Pulsed Echo, Ultrasonic ITX 21 CFR 892.1570 Transducer, Ultrasonic, Diagnostic	
	Premarket Notification:	K120882, concurrence date 30 May, 2012
	Manufacturer:	Bard Access Systems, Inc.

Subject Device Descriptions:

Device Description – Site~Rite Prevue® Ultrasound System	The **Site~Rite Prevue® Ultrasound System** is a portable device that features real-time 2D ultrasound imaging. Additional features include compact size, simple user interface, and various calculations. The system may incorporate various accessories, including an upright stand, A/C adapter, needle guide/gel cap kits, etc. The system includes USB support for storage devices with no external power connections (eg., USB flash drive).
Device Description – Site~Rite Prevue® Ultrasound System	The **Site~Rite Prevue® Ultrasound System** is a portable device that features real-time 2D ultrasound imaging. Additional features include compact size, and simple user interface. The system may incorporate various accessories, including an upright stand, A/C adapter, needle guide, etc. The system includes USB support for storage devices with no external power connections (e.g., USB flash drive).
Device Description – Site~Rite Prevue+® Ultrasound System	The **Site~Rite Prevue+® Ultrasound System** is a portable device that features real-time 2D ultrasound imaging. Additional features include compact size and a simple user interface. The system may incorporate various accessories, including an upright stand, A/C adapter, needle guide, etc. The system includes USB support for storage devices with no external power connections (eg., USB flash drive).

Subject Device Indications for Use/Intended Use:

Indications for Use/Intended Use – Site~Rite Prevue® Ultrasound System	The **Site~Rite Prevue® Ultrasound System** is intended to provide ultrasound imaging of the human body. Specific clinical applications include: ● Adult Cephalic ● Neonatal Cephalic ● Pediatric ● Peripheral Vessel
Indications for Use/Intended Use – Site~Rite Prevue+® Ultrasound System	The **Site~Rite Prevue+® Ultrasound System** is intended to provide ultrasound imaging of the human body. Specific clinical applications include: ● Adult Cephalic ● Neonatal Cephalic ● Pediatric ● Peripheral Vessel

Indications for Use/Intended Use – Pinpoint® Gel Cap and Pinpoint® Needle Guide	The gel cap is intended for use as an ultrasound coupling medium for use with the Site~Rite Prevue® Ultrasound System. The device is intended for use with pediatrics and adults. The needle guides are intended to provide guidance for a needle to intersect an ultrasound beam at a fixed distance below the skin to assist the medical practitioner in placing the tip of a needle in a specific structure. This device is intended for use with pediatrics and adults.

Subject Devices Technological Characteristics:

Technological Characteristics	With respect to the fundamental scientific technology, the subject devices and the predicate device are the same. The subject devices operate identically to the predicate device in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D images. However, the subject devices will utilize a new beamformer board set (ultrasound generator) and accompanying software, which affects ultrasound generation for the subject devices. Design verification has been conducted and test results show that the subject devices are safe and effective for their intended use/indications for use and the difference in technological characteristics did not raise any new questions regarding safety and effectiveness.

Safety & Performance Tests	Verification and validation activities were designed and performed to demonstrate that the subject **Site~Rite Prevue® Ultrasound System** and the **Site~Rite Prevue+® Ultrasound System** met predetermined performance specifications. The following standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device:
IEC 60601-1:2005 CORR. 1(2006), CORR. 2(2007)	Medical Electrical Equipment – Part 1: General Requirements For Basic Safety and Essential Performance – Edition 3
IEC 60601-1-2:2007	Medical Electrical Equipment – Part 1.2: General Requirements For Basic Safety and Essential Performance – Edition 3.1
IEC 60601-2-37:2007	Medical Electrical Equipment – Part 2-37: Particular Requirements For the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitory Equipment

ISO 10993-1:2009	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
NEMA UD 2-2004 (R2009)	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3

The subject devices met all pre-determined acceptance criteria and demonstrated substantial equivalence as compared to the predicate device.

Safety & Performance Tests	Based on the intended use/indications for use, technological characteristics, and safety and performance testing, the subject **Site~Rite Prevue® Ultrasound System** and the **Site~Rite Prevue+® Ultrasound System** meet the minimum requirements that are considered adequate for their intended use and are substantially equivalent in design, principles of operation, and intended use/indications for use to the predicate device, the Site~Rite Prevue® Ultrasound System (K120882). Based on the performance testing, the subject devices, the **Site~Rite Prevue® Ultrasound System** and the **Site~Rite Prevue+® Ultrasound System** are as safe, as effective, and perform as well as the predicate device, the Site~Rite Prevue® Ultrasound System (K120882).